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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,565	05/02/2002	Audrey Goddard	P3230R1C001-168	2399

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EXAMINER

HUNNICUTT, RACHEL KAPUST

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/063,565

Applicant(s)

EATON ET AL.

Examiner

Rachel K. Hunnicutt

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 5-13.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments with respect to the rejection of claims 5-13 under 35 U.S.C. 101 have been fully considered but have not been found to be persuasive. Applicants argue that Example 18 enables one of skill in the art to quantitatively measure the difference in expression of the PRO1106 polypeptide in at least one type of human esophageal tumor when compared to normal esophageal tissue. Applicants argue on p. 6 of the response that the differential expression of the PRO1106 mRNA confers utility upon the PRO1106 polypeptide. Applicants argue that the utility of the claimed polypeptides is that they can be used as diagnostic tools for the detection and diagnosis of certain types of esophageal tumors. This utility is not a substantial utility. Applicants have not taught what kind of esophageal tumors could be diagnosed. Applicants have not taught baseline levels of expression, nor have Applicants provided numerical values for the levels of overexpression and underexpression. One skilled in the art would not know whether the protein is actually more highly expressed in certain tumors or whether the "overexpression" is due to aneuploidy which occurs frequently in cancer. Merely stating that the polypeptide is "more highly expressed" is simply an invitation to experiment.

A substantial utility, by definition, is a utility that defines "real world" use, and a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility. In the instant case, the overexpression of PRO1106 polypeptides in esophageal tumors (if significant), at the most, is an interesting invitation for further research, experimentation and confirmation as to whether PRO1106 is useful as a diagnosis marker. These further research and experimentation, however, is part of the act of invention, and until it has been undertaken, the claimed invention is not considered substantial.

The rejection of claims 5-13 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained for reasons of record on p. 4 of paper no. 1004.

The rejection of claims 5 and 12-13 under 35 U.S.C. 112, first paragraph, as not being enabled for polypeptides at least 99% identical to SEQ ID NO: 58 is maintained for reasons of record on p. 4-5 of paper no. 1004. One skilled in the art would not know how to engineer a polypeptide 99% identical to SEQ ID NO: 58 wherein it is more highly expressed in esophageal tumors than in normal esophagus tissue.

The rejection of claims 5 and 12-13 under 35 U.S.C. 112, first paragraph, as not complying with the written description requirement is maintained for reasons of record on p. 5-6 of paper no. 1004. Applicants have only shown that the polypeptide comprising SEQ ID NO: 58 may be overexpressed in esophageal tumors, not polypeptides 99% identical to SEQ ID NO: 58.


JANET ANDRES
PRIMARY EXAMINER